

Application No. 10/500,838

5

Docket No.: 56792(71699)

**REMARKS**

Claims 3-5, 9-12, 34, 39 and 62 are pending in the application. Claims 10-12 have been amended by the amendments presented herein. Accordingly, once the amendments presented herein have been entered, claims 3-5, 9-12, 34, 39 and 62 will remain pending. No new matter has been added.

***Rejection of Claims 3-5, 9, 10-12, 34, 39, and 62 Under 35 U.S.C. 112***

The Examiner has rejected claims 3-5, 9-12, 34, 39 and 62 under 35 USC 112, first paragraph failing to comply with the written description requirement. The examiner believes that the specification does not teach "wherein an increase in the levels of one or more of Markers II and III, or a decrease in the levels of one or more of Markers I, IV, V or VII is indicative that the subject has ovarian cancer." Applicants disagree. Applicants point the Examiner's attention to Example 1, page 47 of the application. The results of Example 1 clearly indicate that "at 9.2kD, 19.8kD, and 60kD showed higher expression levels on average among the specimens from the cancer patients compared to the controls while the remaining peaks demonstrated the inverse expression pattern." The marker of 9.2kD is Marker II and the marker of 19.8kD is Marker III. Accordingly, the application as filed provides support for the amendment presented in the last response to office action.

Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw this rejection.

***Rejection of Claims 9-12 Under 35 USC 112***

The Examiner has rejected claims 9-12 as being indefinite in the recitation of the term "known biomarker". Based on the teachings in the specification, Applicants believe the term "known biomarker" is clear and definite. However, in the interest of expediting prosecution, and in no way acquiescing to the validity of the Examiner's rejection, Applicants have amended the claim to recite "additional biomarker".

BOS2 701753.1

Application No. 10/500,838

6

Docket No.: 56792(71699)

Applicants believe that this amendment will overcome the Examiner's rejection, and therefore, respectfully request withdrawal of this rejection.

***Rejection of Claims 3-5, 9-12, 39 and 62 Under 35 U.S.C. 102(e)***

The Examiner has rejected claims 3-5, 9-12, 39 and 62 as being anticipated by US Patent Application Publication No.: 2003/0003479. Specifically, the Examiner indicates that the '479 publication discloses methods for detecting, characterizing and staging ovarian cancers comprising correlating changes in levels of expression of marker **genes** with the presence of ovarian cancer. Applicants respectfully traverse this rejection.

As previously indicated, the markers disclosed in the '479 application are nucleic acid markers and not polypeptide markers. The Examiner is of the opinion that that '479 publication is enabling for detecting, characterizing and staging ovarian cancer by detecting the presence of one or more polypeptides corresponding to the nucleic acid molecules identified in the '479 application. However, this is not the case. The '479 publication provides no evidence of altered expression levels of the polypeptides corresponding to the identified nucleic acid molecules in disease state, i.e., in cancerous tissue.

Moreover, the Examiner indicates that markers O504, O512, and O517 correspond to Applicant's markers V, IV, and VII, respectively. Claim 1, as pending, is directed to a method of detecting and diagnosing ovarian cancer by measuring at least one of the identified protein biomarkers in a subject sample, and correlating the measurement of one or more protein biomarkers with a diagnosis of ovarian cancer, wherein an increase in the levels of one or more of Markers II and III, or a ***decrease in the levels of one or more of Markers I, IV, V or VII is indicative that the subject has ovarian cancer.*** The '479 publication teaches that the biomarkers set forth in Table I (including O504, O512, and O517) are up-regulated in cancerous samples. The '479 publication states that "[m]arker genes for which significant increases in the levels of expression in cancer-related samples relative to non-cancerous samples were observed and listed in Table 1" (see paragraph [0343]).

BOS2 701753.1

Application No. 10/500,838

7

Docket No.: 56792(71699)

Accordingly, the '479 publication does not anticipate the pending claims. Applicants respectfully request reconsideration and withdrawal of the foregoing rejection.

***Rejection of Claims 3-5, 9-12, 39 and 62 Under 35 U.S.C. 103(a)***

The Examiner has rejected claims 3-5, 9-12, 39 and 62 as being unpatentable over US Patent Application Publication No.: 2003/0003479 in view of US Patent Application Publication No.: 2003/0147106 and US Patent 5,650,291.

As indicated above, the '479 publication does not teach or suggest the claimed invention. Moreover, the '106 publication and the '291 patent do not make up for the deficiencies of the '479 publication. Accordingly, the combination of these documents would not put one of skill in the art in possession of the instant invention.

Therefore, Applicants respectfully request the reconsideration and withdrawal of the foregoing rejection.

BOS2 701753.1

Application No. 10/500,838

8

Docket No.: 56792(71699)

CONCLUSION

In view of the above amendment, applicant believes the pending application is in condition for allowance.

Dated: October 30, 2008

Customer Number 21874

Respectfully submitted,

By, 

Jonathan M. Sparks, Ph.D.

Registration No.: 53,624

EDWARDS ANGELL PALMER & DODGE  
LLP

P.O. Box 55874

Boston, Massachusetts 02205

(617) 517-5543

Attorneys/Agents For Applicant

BOS2 701753.1